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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/832,292	04/10/2001	Alexey Ryazanov	601-1-098CIP	8327

23565 7590 09/23/2003

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EXAMINER

HUTSON, RICHARD G

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 09/23/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/832,292

Applicant(s)

RYAZANOV, ALEXEY

Examiner

Richard G Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,5 and 14-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4,5 and 14-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Applicants amendment of the specification, amendment of claims 4, 14 and 16, and cancellation of claims 1-3, 6-13 and 18-48, Paper No. 14, 6/12/2003, is acknowledged. Claims 4, 5 and 14-17 are at issue and are present for examination.

Applicants' arguments filed on 6/12/2003, Paper No. 14, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Priority

The granting of applicants claim of priority for the DNA sequence of SEQ ID NO: 34 to the instant application, filed 4/10/2001, as there is no support for this sequence in application Serial No. 09/623,131, remains proper.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 5, 14-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection was stated in the previous office action. Claim 4 (5, and 14 dependent on) and newly amended claims 14 (claim 15 dependent on) and 16 are indefinite in the recitation of a heart alpha kinase, as it is unclear what features define a "heart" alpha kinase from other alpha kinases. While page 5 defines the characteristics of an alpha kinase, the only definition of the term heart alpha kinase is on page 26 and is wholly unclear as to the scope of proteins encompassed. While it is clear applicants intend this term to encompass the proteins of SEQ ID NOS: 35 and 37 it is also clear that this term is intended to include other similar proteins also. However, the definition does not make clear what the metes and bounds of this term are.

In response to this previous rejection, applicants submit that the term "heart alpha kinase" is clear to the skilled artisan, based on a reading of the pending claims and the description and definition provided in the specification. Applicants point to the specification pages 76 and 83-85, as defining "heart alpha kinase" as a protein predominantly expressed in the heart and as a large protein of more than 1000 amino acids with a typical alpha kinase catalytic domain located at the C-terminus.

Applicants argument is not found persuasive on the basis that this rejection as previously stated was made on the basis that it was unclear what features define a "heart" alpha kinase from other alpha kinases. That is what characteristics with the exception of its amino acid sequence and the place in which it is predominantly expressed, distinguish a "heart" alpha kinase from a "melanoma", "kidney", "skeletal muscle" and "lymphocyte" alpha kinase. Applicants have described what defines an alpha kinase (i.e. 1000 amino acids and a typical alpha-kinase catalytic domain located

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at the C-terminus) but applicants have distinguished between each of the "different types" of "alpha kinases such that one would know whether they were in possession of a "heart", "melanoma", "kidney", "skeletal muscle" or "lymphocyte" alpha kinase.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection was stated in the previous office action. In response to this rejection, applicants have amended claim 16 from which claim 17 depends and argue this rejection as it applies to the amended claims.

Applicants submit that claims 16 and 17 are directed to unicellular host cells transformed with DNA encoding a heart alpha kinase, wherein said DNA consists of the DNA of SEQ ID NO: 34, DNA sequences hybridizing thereto under standard stringency hybridization conditions and DNA sequences that encode the same amino acid sequence of SEQ ID NO: 34 or its hybridizing sequences. Applicants submit that these DNAs are structurally and functionally related as heart alpha kinases, as defined by the specification and as noted as above. Applicants argument is not found persuasive on the basis that claims 16 and 17 are not directed to "unicellular host cells transformed

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with DNA encoding a heart alpha kinase, wherein said DNA consists of...", but rather the rejected claims are directed to "unicellular host cells transformed with DNA encoding a heart alpha kinase **or a fragment thereof**, wherein said DNA consists of..." Thus since the genus of transformed unicellular host cells comprises those host cells transformed with a DNA sequence that encodes a "fragment thereof" a heart alpha kinase, and said fragments of a heart alpha kinase need not necessarily have alpha kinase activity, applicants assertion that the DNAs, encompassed within the claimed unicellular transformed host cell, share a functional relationship is not correct, as many of those DNAs which encode a fragment of a heart alpha kinase will not encode a polypeptide with alpha kinase activity.

Therefore, as previously stated, many structurally and functionally unrelated DNAs are encompassed within the scope of these claims, including partial DNA sequences. The specification discloses only a two species of the claimed genus (those host cells transformed with SEQ ID NOS: 34 and 36) which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 16 and 17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a host cell transformed with a DNA molecule comprising SEQ ID NO: 34, does not reasonably provide enablement for any host cell transformed with any DNA sequence which encodes a fragment of SEQ ID NO: 34 or a DNA sequences which hybridizes to a fragment of a DNA sequence which encodes SEQ ID NO: 34. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection was stated in the previous office action. In response to this rejection, applicants have amended claim 16 from which claim 17 depends and argue this rejection as it applies to the amended claims.

Applicants submit that while some experimentation to make, test and use host cells would be necessary, such experimentation would utilize known methods and standard skills and would not constitute undue experimentation and applicants support their submission by reference to those factors considered in determining whether undue experimentation is required, as summarized in *In re Wands* (858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)). In view of applicants submission (i.e. applicants analysis of each of the Wands factors), applicants submit that given the guidance provided by the specification, the well known criteria or parameters for making and testing of host cells, and the significant level of skill in the art a person of ordinary skill in the art could, without undue experimentation, make and use the host cells encompassed by the claims. Applicants argument is not found persuasive for the same reason as stated in

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the above rejection based on a lack of adequate written description, contrary to applicants assertion, claims 16 and 17 are not directed to “unicellular host cells transformed with DNA encoding a heart alpha kinase, wherein said DNA consists of...”, but rather the rejected claims are directed to “unicellular host cells transformed with DNA encoding a heart alpha kinase **or a fragment thereof**, wherein said DNA consists of...”

Thus since the genus of transformed unicellular host cells comprises those host cells transformed with a DNA sequence that encodes a “fragment thereof” a heart alpha kinase, and said fragments of a heart alpha kinase need not necessarily have alpha kinase activity, applicants assertion that the DNAs, encompassed within the claimed unicellular transformed host cell, share a functional relationship is not correct, as many of those DNAs which encode a fragment of a heart alpha kinase will not encode a polypeptide with alpha kinase activity and thus applicants have not enabled the rejected claims on the basis that many of the encompassed transformed host cells are transformed with DNA which encodes a protein of unknown function. Thus applicants have not enabled how to use these transformed host cells.

The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 16 and 17 are rejected under 35 U.S.C. 102(a) as being anticipated by Scharenberg et al. (WO 00/40614, July 2000).

This rejection was stated in the previous office action. In response to this rejection, applicants have amended claim 16 from which claim 17 depends and argue this rejection as it applies to the amended claims.

Applicants submit that Scharenberg et al. neither discloses every element of the rejected claims nor enables one skilled in the art to isolate or make the anticipating subject matter, specifically the claimed host cells. In support of applicants position, applicants submit that the sequence of the SOC-2/CraC-1 kinase, which is completely different from the heart alpha kinase sequence, does not anticipate or even suggest the particular alpha kinase sequences of the instant application and further does not disclose or suggest the host cells transformed with heart alpha kinase sequence. While it is acknowledged that Scharenberg et al. does not teach or suggest the particular alpha kinase sequences of the instant application (i.e. SEQ ID NO: 34) and further does not disclose or suggest host cells transformed with the heart alpha kinase sequence

(i.e. SEQ ID NO: 34), Scharenberg et al. does teach expression vectors comprising and host cells transformed with a DNA which encodes protein named SOC-2/CraC-1 which has kinase activity. It is noted that whether the encoded protein has kinase activity is not currently a limitation of the rejected claims. Regardless, the nucleic acid taught by Scharenberg et al. is clearly encompassed by a "DNA sequence or degenerate variant thereof, which encodes a heart alpha kinase, **or a fragment thereof**, selected from the group consisting of a., b. and c." Further applicants attention is directed to newly amended part c. The nucleic acid taught by Scharenberg et al. is clearly encompassed by "DNA sequences that encode an amino acid sequence encoded by any of the foregoing DNA sequences (i.e. SEQ ID NO: 34)." For instance, SEQ ID NO: 34 encodes a polypeptide which comprises 1597 amino acids while this polypeptide has an associated amino acid sequence of SEQ ID NO: 35, SEQ ID NO: 35 comprises many additional amino acid sequences (i.e. fragments such as Leu-Leu). For example Scharenberg et al. teach cells transformed with the DNA sequence of SEQ ID NO: 1 which encodes SEQ ID NO: 2 as well as many "amino acid sequences" within SEQ ID NO: 2 such as "Leu-Leu", an amino acid sequence which is encoded by SEQ ID NO: 34. Thus claims 16 and 17 remain anticipated by Scharenberg et al.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Richard G Hutson, Ph.D.
Primary Examiner
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